Chapter 9
Quality Assurances and Controls for Remedial Actions at LLRW and MW Sites

9-1. Introduction

a. Cleanup of sites. This chapter provides guidance to any party involved with the cleanup of controlled or uncontrolled LLRW AND MW sites. Overall guidance is obtained from ER 1110-1-12, "Quality Management." General policy and guidance for establishing quality management procedures in the execution of construction contracts are provided by ER 1180-1-6, "Construction Quality Management." Construction quality management programs are well-established within USACE and apply directly to LLRW and MW site remediation activities. The guidance presented herein is directed towards quality assurance/quality control (QA/QC) of remedial actions specifically at LLRW and MW sites and is modeled after the document "Quality Assurance Guidance for Low-Level Radioactive Waste Disposal Facility," NUREG-1293 (NRC 1989). The document describes 18 quality control criteria which are basic to any QA program, but specifically addresses LLRW disposal. Because M W is characterized by a radioactive component, these quality control criteria are directly applicable to MW site restoration. The guidance presented herein describes the same 18 criteria (some are identical) while addressing remedial operations, including onsite disposal of radioactive waste. This guidance is oriented towards the actual remedial actions. Similar QA/QC considerations are required during the remedial investigation/feasibility study phases of effort at the site. For purposes of chemistry (including radiochemistry) data acquisition during remedial investigations, ER 1110-1-263 will be followed. Specifically, investigative data quality objectives are to be developed by the contractor for the areas of chemical, radioactivity, and geotechnical data acquisition and interpretation. These data quality management objectives will then be implemented through data acquisition plans (e.g., CDAP), which will specify the controls on the quality of the data-gathering efforts.

b. Responsibilities. Remedial operations often involve more than one responsible party and supporting organization, yet one party must be solely responsible for the content and success of the QA program. The responsible party must oversee all contractors' and subcontractors' QA programs and assure their compliance with the criteria presented here. The responsible party will be assumed to be USACE in the following discussion.

9-2. Organization of QA/QC Programs

The lead agency concerned with an MW site shall be responsible for the establishment and execution of the QA program. DOE Order 5700.6B is a directive written specifically for QA at Hanford, though it will provide insight into broadly applicable QA program requirements at DOE sites. The work of establishing and executing the QA program may be delegated to contractors, agents, or consultants, but ultimate responsibility and control are retained by the leader. The lead agency will establish, define, and delineate in writing the functions and responsibilities of each delegated organization required to perform "quality achieving" and "quality assuring" activities. The persons and organizations performing quality assuring functions must be allowed sufficient authority to identify problems with quality, recommend solutions, and verify implementation of solutions. To ensure accomplishment of QA goals, individuals assigned the responsibility for ensuring effective execution of any portion of the QA program should have direct and meaningful access to the levels of management necessary for fulfillment of this responsibility.

9-3. QA Program Plan

a. Plan development. The lead agency will provide, as early as possible, a QA program plan (QAPP) that complies with current guidance. EPA (1983) 600/4 - 83/004 provides guidelines and specifications for preparing the QAPP. The QAPP will document policies, procedures, and guidance which should be carried out through the entire remediation process, from characterization and licensing for disposal through monitoring and closing of a site. Activities, structures, systems, and components of the remediation program will be identified along with major participating organizations and their designated functions.

b. QAPP objective. The QAPP will provide control over remedial activities effecting quality and address the need for special controls, processes, test equipment, tools, and skills to attain the required quality of defined activities, structures, systems, and components.

9-4. Quality Control

The QA program will provide indoctrination and training for personnel to ensure understanding of QA requirements and the importance of the requirements. Environmental training for HW and LLRW personnel is offered by USACE and the EPA. The QA program should be

reviewed regularly for adequacy and should be in effect until closure of the site.

a. Design controls.

(1) Designs are controlled by ER 1110-345-100, "Design Policy for Military Construction, " ER 1110-345-700, "Design Analyses, " ER 1110-345-710, "Drawings," and ER 1110-345-720, "Construction Specifications. "

(2) Design controls should ensure that required regulations are correctly translated into specifications, drawings, procedures, and instructions for remedial action. This section gives a brief description of necessary design controls. Specifically, geotechnical aspects of remedial design controls are extensively reported in NUREG/CR-3356, "Geotechnical Quality Control: Low Level Waste and Uranium Mill Tailings Disposal Facilities" (Johnson, Spigolon, and Lutton 1983).

(3) The design control program should be documented and implemented before design work begins. The design control program should specify appropriate quality standards to be included in design documents. Any deviation from such standards shall be documented. The program should contain measures to ensure suitability of selected materials, parts, equipment, and processes essential to the functions of the systems, structures, and components of the operation.

(4) Design control includes the following:

(a) Measures to ensure verification or checking of design adequacy.

(b) Identification of positions or organizations responsible for design verification.

(c) Description of the measures taken to ensure verification is performed by individuals other than those responsible for the original design.

b. Procurement document control. Procurement documents for the purchase of materials, equipment, or services should include or reference applicable regulatory requirements, design bases, and other requirements needed to assure adequate quality. Qualified personnel should review and agree on the adequacy requirements stated in procurement documents. This review should be documented. Procurement documents must clearly describe the procedures to be followed, records to be generated and retained for field services, and identification of documentation to be prepared and submitted to the purchaser.

c. Instructions, procedures, and drawings. Approved instructions, procedures, and drawings are needed for the performance of designated activities, structures, systems, and components of the remedial action to provide criteria for verification and ultimately demonstrate that the action was performed according to the technical requirements.

d. Document control.

(1) Objective. Measures shall be established which control the issuance of documents (e.g., instructions, procedures, drawings) which describe all activities pertaining to quality. These documents should be reviewed for adequacy and approved by authorized personnel before being released and used at the location of the activity. Changes to the documents shall be subject to the same procedure of review and approval as the original documents.

(2) Litigation. Document control is extremely important in the event of litigation. EPA report No. 330/9-78-00 l-R, "National Enforcement Investigation Center, Policies and Procedures, " (EPA 1978) has an extensive program for document control which should be closely reviewed even if litigation is not pending.

(3) Remediation. Document control specifically for remediation measures is addressed in the EPA report No. 540/G-85/002 (EPA 1985a), "Guidance on Remedial Investigations Under CERCLA. "

e. Control of purchased material, equipment, and services. Purchasing controls should ensure that material, equipment, and services purchased conform to procurement document requirements, and appropriate evaluation and selection of possible sources are reviewed before the purchase. Also, documented evidence of procured items meeting requirements of procurement documents should be furnished by the supplier upon receipt of the items. This document should be kept onsite and available before the item(s) is used. Inspection of the suppliers' facility by the purchaser, in accordance with written procedure, should be conducted during any phase of design, manufacture, or testing of the procured item to ensure quality. Periodic verification of suppliers' certificates of conformance should be performed to ensure validity.

f. Identification and control of material, parts, and components. This criterion ensures formal control and identification of items (e.g., core, laboratory test samples, materials to be used in construction, and materials found defective) used during all phases of remedial

action. Items should be properly identified, where appropriate, with identification on the item itself or maintained on records traceable to the original item. Identification measures should be designed to prevent the use of incorrect or defective material, parts, and components.

g. Control of processes. Processes affecting the quality of items or services should be described by formal instructions, procedures, drawings, checklists, or other appropriate means. The description should specify the level of operator skills required for performing the process. Qualification records of personnel associated with said processes should be established and kept current.

h. Inspection. Inspection is a means of accepting or rejecting completed work. It can also verify that work or prior inspections have been performed properly.

(1) Inspection objectives. A program for inspection should describe measures to ensure that inspection personnel are qualified and independent of the activity being inspected, indirect control by monitoring is used if direct inspection is inadequate, both inspection and process monitoring are conducted when necessary to ensure quality, inspection procedures will be available before the inspections are performed, and replaced, modified, or repaired items are inspected as original items.

(2) Inspection documentation. Documents will be necessary to identify mandatory inspection hold points that require witnessing or inspecting, beyond which work may not proceed without consent of a designated individual.

i. Test control. A test program shall be established to ensure satisfactory performance of structures, systems, and components. Tests shall be performed by qualified personnel in accordance with written test procedures that contain acceptable limits and requirements from applicable design documents. Test procedures shall ensure all test prerequisites are met and adequate instrumentation and suitable environmental conditions are available. Test results should be documented and retained onsite as verification that test requirements have been satisfied.

j. Control of measuring and test equipment. Requirements for the calibration of monitoring equipment are contained in AR 40-14, "Control and Recording Procedures for Occupational Exposure to Ionizing Radiation," and AR 385-11, "Ionizing Radiation Protection." Procedures for carrying out the calibration of monitoring equipment are given in Technical Bulletin (TB) 9-6665-285-15, "Army Calibration Program for Radiac Meters."

k. Handling, storage, and shipping. Measures should be made to control the handling, storage, packaging, and shipping of items affecting the quality of remedial operations. Special attention must be paid to the care of samples obtained for site characterization and design. These samples must be prevented from loss, damage, deterioration, and misidentification and, if necessary, special provisions should be specified to prevent contamination or damage due to adverse environmental conditions. All items should be handled in accordance with design and specification requirements. Identification of samples and items must be verified and maintained when being transported or transferred from one organization's responsibility to another.

1. Inspection, test, and operating status. The purpose of this criterion is to identify the status of tested and/or inspected items. Measures should be taken to tag, stamp, or label items with results of the most recent test or inspection to prevent the inadvertent use of defective items and the bypassing of such inspections or tests. In addition, the operating status of structures, systems, and components of the remedial operation should be identified to preclude inadvertent operation.

m. Nonconforming materials, parts, or components. A procedure should be established for control of materials, parts, or components that do not conform to requirements to prevent their use. Measures should provide for appropriate identification, documentation, segregation, deposition, and notification to affected organizations. These items should then be reviewed and accepted, rejected, repaired, or reworked in accordance with documented procedures.

n. Corrective actions. Corrective measures should be described which ensure that conditions adverse to quality, such as failures, malfunctions, deficiencies, derivations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, measures should be taken to identify, document, and report to management the cause of the condition and the corrective action needed. Significant conditions are those which seriously affect safety, reliability, or performance.

o. Quality assurance records. Quality assurance records are the most important evidence that quality-assuring activities have been properly performed. These

records should be carefully controlled with specifications for content, identification, storage, and access. Record content should include as a minimum the following: operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and material analysis. Additional related data can be included such as personnel, equipment, and procedure qualifications. Inspection and test records need to identify the inspection or data recorder, the type of observation, the results, the acceptability, and corrective action taken, if any. A plan should be established describing the retention of records, such as duration, location, and assigned responsibility in accordance with applicable regulatory requirements.

p. Audits, surveillance, and managerial controls. A comprehensive plan of audits, surveillance, and managerial controls should be established to determine the effectiveness of the quality assurance program. Periodic audits should be conducted, according to written procedure, by qualified personnel not directly responsible for the area being audited. The results of the audit shall be documented and reviewed by management personnel having responsibility in the area audited. The plan should include frequency of audits; documentation, review, and record maintenance of the audit program; follow-up action, including correction and surveillance. The plan should measure and record the status of the remedial action as it relates to meeting regulatory requirements and identifies problems in a real-time framework for timely mitigation.